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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/752,793	01/07/2004	Mario Rosario Carlone JR.	P06276US01-PHI 1334	5128

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EXAMINER

FOX, DAVID T

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 12/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/752,793

Applicant(s)

CARLONE ET AL.

Examiner

David T. Fox

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11, 12 and 17 is/are allowed.
- 6) ☒ Claim(s) 1-10, 13-16 and 18-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 18 October 2005 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 19, 23 and 24 and dependents are indefinite in their recitation of "plant of claim 11...further defined as... comprising a single locus conversion [or a gene or a transgene]". It is confusing to characterize the plant of claim 11, which has a finite and particularly defined genome comprising a particular allele at every individual locus, as simultaneously comprising additional transgenes or single locus conversions. Additionally, it is confusing to characterize the male fertile plant of claim 11 as simultaneously male sterile.

Claim 22 is indefinite in its recitation of "yield enhancement" and "improved nutritional quality" as these are relative terms for which no comparative standard is provided.

Claim 30 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim is drawn to a plant breeding method comprising obtaining a molecular marker profile of the exemplified inbred, inducing doubled haploidy of F1 hybrid seed produced from the inbred, and then selecting progeny that retain the molecular marker profile of the exemplified inbred. However, no basis in the specification was provided for these terms, and the Examiner can find none. Accordingly, the claim is directed to NEW MATTER.

Claims 1-10, 13-16 and 18-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated in the last Office action for claims 1-10.

New claims 13-16 and 18 are included in the rejection because they are drawn to F1 (and beyond) products analogous to previously rejected claims 1-10. New claims

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19-21 are included in the rejection because they are drawn to plants comprising a multitude of uncharacterized single locus conversions or transgenes. New claims 19-24 are included because they are directed to plants which comprise a finite and completely characterized genome and which exhibit a finite set of traits, and which simultaneously comprise additional genes conferring additional traits, wherein no plants of this type were reduced to practice or otherwise described. Furthermore, new claims 19-24 read on plants containing uncharacterized genetic material linked to the source of the "single locus conversion". New claims 25-30 are included because they are drawn to methods of using uncharacterized descendants of the exemplified inbred in a multitude of outcrossing steps to uncharacterized breeding partners.

Claims 1-10, 13-16 and 18-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, as stated in the last Office action for claims 1-10.

New claims 13-16 and 18 are included in the rejection because they are drawn to F1 (and beyond) products analogous to previously rejected claims 1-10, wherein one skilled in the art would not know how to use said products, wherein at least half of their genome is uncharacterized and confers a multitude of unknown traits.

New claims 19-21 are included in the rejection because they are drawn to plants comprising a multitude of uncharacterized single locus conversions or transgenes, wherein one skilled in the art would not know how to use plants containing

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uncharacterized or unspecified transgenes or single locus conversions conferring unspecified traits. Furthermore, one skilled in the art would not be able to make "single locus conversions" in the absence of at least four backcrossing steps, due to the linkage drag and epistasis taught by Melchinger and Stuber cited previously, and as taught by Murray et al discussed below.

Murray et al teach that linkage drag is a common phenomenon in corn breeding, and that the equivalent of 10 backcrosses resulted in the retention of 10% of the unwanted donor parent genome, in contrast to the predicted less than 1% (see, e.g., pages 82-84).

New claims 19-24 are included because they are directed to plants which comprise a finite and completely characterized genome and which exhibit a finite set of traits, and which simultaneously comprise additional genes conferring additional traits. One skilled in the art would not know how to make such plants. Furthermore, new claims 19-24 read on plants containing uncharacterized genetic material linked to the source of the "single locus conversion". One skilled in the art would not know how to use plants exhibiting unknown traits conferred by said uncharacterized linked genetic material.

New claims 25-30 are included because they are drawn to methods of using uncharacterized descendants of the exemplified inbred in a multitude of outcrossing steps to uncharacterized breeding partners. One skilled in the art would not know how to use said plants with uncharacterized genomes and exhibiting unspecified traits. Additionally, the specification does not provide guidance for the use of doubled haploidy

of F1 hybrids, or the tracking of molecular marker profiles from inbred to hybrid or descendants thereof.

Furthermore, claim 22 is drawn to the introgression of a quantitatively inherited trait such as yield enhancement or improved nutritional quality. Claims 29-30 are drawn to the use of molecular markers in a corn breeding program.

"Value-added traits" such as those of claim 22 are conferred by multiple genes, or quantitatively inherited, wherein such traits are incorporated into a desired genetic background via molecular markers. However, the use of molecular markers in corn breeding, as newly claimed, is unpredictable. Goldman et al teach that the use of molecular markers to facilitate the identification of chromosomal regions associated with quantitatively inherited traits is hampered by the different linkage maps generated when different breeding lines are used as parents (see, e.g., page 909, column 2, top paragraph; paragraph bridging pages 911 and 912; paragraph bridging pages 912 and 913). In addition, inconsistent results were observed regarding the correlation of particular quantitatively inherited traits (see, e.g., Goldman et al, page 910). Furthermore, quantitative traits involved in the newly claimed improved nutritional quality, such as oil or protein content, are inversely proportional to kernel size (see, e.g., Goldman et al, page 908, column 1, middle paragraph and column 2, bottom paragraph). Murray et al also teach the unpredictability inherent in molecular marker-assisted breeding, given the failure to identify molecular markers which are actually specific for particular cultivars (see, e.g., page 79, second full paragraph).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by each of Kevern (US 5,850,009) or Carlone (US 5,763,755).

The claim is drawn to seeds produced on an F1 hybrid plant. The F1 hybrid plant has the exemplified inbred as one parent, and any other corn plant of any genotype as its other parent. Upon selfing of the F1 hybrid to produce the claimed seed, the progeny will segregate into the original parental genotypes, including the non-exemplified corn parent. Such progeny are indistinguishable from any known non-exemplified corn plant, including those taught by each of Kevern and Carlone.

See *In re Best*, 195 USPQ 430, 433 (CCPA 1977), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

Claims 1-15 and 17-30 are deemed free of the prior art, as stated previously for claims 1-10.

Claims 11-12 and 17 are allowed.

Applicant's arguments filed 18 October 2005 have been fully considered but they are not persuasive.

Applicant urges that the written description rejection is improper, given the disclosure of a structural feature (the exemplified inbred's genome) which is correlated with the function of the morphological traits of the exemplified inbred, the deposit of the exemplified inbred which is sufficient as taught by *Enzo*, and the teachings of *J.E.M. Ag. Supply* and *Ex parte Garing*.

The Examiner maintains that the exemplified inbred's genome is completely non-predictive of any function when present in a descendant plant, namely any trait of the resultant F1 hybrid, since each trait exhibited by the F1 hybrid is equally dependent upon the genotype of the second non-exemplified inbred. The genus of all F1 hybrids produced from the exemplified inbred and a multitude of non-exemplified breeding partners will possess little if any of the traits of the exemplified inbred.

Regarding the deposit of the exemplified inbred, the Examiner maintains that such deposit is not sufficient to describe descendants thereof. The teachings of *Enzo* have been rebutted previously. Regarding *J.E.M.*, the Examiner notes that the Decision pertained to the patentability of claims under 35 USC 101, rather than 35 USC 112, first paragraph. Regarding *Garing*, the Examiner notes that the Board Decision was unpublished and therefore non-precedential.

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Applicant urges that the enablement rejection is improper, since the conserved genetic material from the exemplified inbred will confer a particular function (i.e. set of morphological traits) to any F1 hybrid or other descendant thereof, wherein one skilled in the art would know how to use said descendants exhibiting said traits. The Examiner maintains that the genetic contribution of the exemplified inbred is completely non-predictive of any individual trait or combination thereof exhibited by any F1 or other descendant.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is 571-272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

November 27, 2005

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

